UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,642	02/01/2002	Richard Fayrer-Hosken	235.00310101	1056

26813 7590 09/22/2004

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,642	FAYRER-HOSKEN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) 12-28 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-11 as they read on a polypeptide, in the reply filed on August 2, 2004 is acknowledged. The traversal is on the ground that there is no undue search burden. This is not found persuasive because of the reasons set forth in the restriction requirement dated July 1, 2004.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-28 are pending in this application.

Claims 12-28 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-11, as they read on a polypeptide sequence, are under consideration in the instant application.

Applicant's IDS, filed February 11, 2003 is acknowledged and considered. Some references have been considered but are lined through because they do not contain a publication date. See 37 C.F.R. 1.97 and 1.98.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of a fertility impairing vaccine comprising avian zona pellucida protein in birds, does not reasonably provide enablement for the use of a fertility impairing vaccine comprising avian zona pellucida protein in all animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has disclosed methods for how to make a fertility impairing vaccine containing avian zona pellucida proteins (aZP) by isolating material from the perivitelline membranes of laid eggs or ovarian follicles and incorporating this material into a vaccine composition (pages 14-16, Examples I and II). Doses and methods of using such a vaccine are disclosed from page 12, line 10 to page 14, line 13. The scope of the claimed invention is quite broad, as the claims do not recite an intended patient population, yet the specification clearly indicates that the intended patient population for such a vaccine encompasses all oocyte-producing organisms that are capable of voluntary mobility (page 11, lines 8-9). Further, the claims recite a fertility impairing vaccine, but the specification does not appear to clearly define this term. Guidance concerning the terms immunocontraceptive and immunosterilant can be found (page 11, lines 18-20), and in animals that ovulate once per estrus cycle fertility impairment is equivalent to contraception. Animals that ovulate multiple eggs may have reduced fertility and still conceive, albeit with a lower number of resulting offspring. Applicant

does not appear to indicate any level of diminution that is required to meet the intended use limitation of fertility impairment.

Brown et al. (U.S. Patent number 6,790,457) teach a vaccine comprising avian inner perivitelline layer proteins that is administered to birds, but Brown et al. do not appear to indicate its administration to non-avian species (see entire document, especially the claims). Bowen (WO 93/14786, reference B5 on Applicant's IDS dated 2/14/03) teaches on page 24, lines 1-6, "Due to the wide degree of structural and functional diversity among zona pellucida proteins of different species, it cannot be assumed that a vaccine based on zona pellucida proteins from one species will be as efficacious as a vaccine based on the zona pellucida proteins of a different species." Applicant's Example III is titled "Immunosterilization of Dogs using aZP Vaccine" (page 16, lines 4-28), and this example describes a vaccination protocol for dogs and an assay for measuring the anti-aZP specific antibody titer. Applicant discloses that the immunocontraception and immunosterilization utilities of the vaccine are both dependent on the resulting serum antibody titer of the subject, with immunosterilization being accompanied by ovarian pathology (page 11, lines 20-24). This titer then serves as an indicator of fertility impairment, but there appears to be no indication of what titers are needed to cause sterilization, contraception, or fertility impairment. Evidence appears to be lacking that the administration of the aZP vaccine impairs the fertility of the dogs, either by a failure to conceive pups, a smaller than usual litter size, or even that anti-aZP antibody titers increase after vaccination.

Given the unpredictability of immune responses following heteroimmunizations with zona pellucida antigens, the lack of knowledge in the prior art regarding heteroimmunizations specifically with avian zona pellucida proteins, the lack of a clear working example, and the lack of guidance in the specification as to what specific structures present in aZP are required to produce a vaccine having fertility impairing properties, it appears that an undue quantity of experimentation would be required by a person of skill in the art to make and use the full breadth of Applicant's fertility impairing vaccine.

4. Claims 1-11 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

There is insufficient written description encompassing "an immunogenic fragment thereof" in claims 1-11, and there is also insufficient written description encompassing "a T cell epitope, a helper T cell epitope, and a B cell epitope" in claims 1 and 9 because the relevant identifying characteristics such as structure of other physical and/or chemical characteristics of the "immunogenic fragments" or "epitopes" encompassed by the claimed invention are not set forth in the specification as filed.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for

purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

The instant specification discloses on page 6, lines 3-8, that "Immunogenicity ... can be determined...by analyzing anti-aZP fragment antibodies in serum. An immunogenic peptide fragment preferably contains... at least about 20 amino acids." Also disclosed on page 6, lines 9-27, is that "The epitopes can be derived from the species to which the vaccine is to be administered, from the species that was the source of the zona pellucida protein or immunogenic fragment thereof, or from any other species, including a virus, bacterium, or parasite." The specification does not appear to disclose any specific structure (sequence) that is associated with the "immunogenic fragments" that is essential to their activity as an immunogen, nor does it appear to disclose any specific structure (sequence) that is associated with the "epitopes" that is essential to their immunological activity as "epitopes". The instant claims also do not appear to provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus of "immunogenic fragments" or

"epitopes", a person of skill in the art would not know which sequences are essential and which sequences are non-essential for identifying an "immunogenic fragment" or "epitope", nor would they know what sequence length is required of an "epitope". Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus of "immunogenic fragments" or the genus of "epitopes", one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-6, 10 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Waclawek et al. (Biology of Reproduction, 1998; 59:1230-1239, reference C90 on Applicant's IDS dated 2/14/03, see entire document).

Waclawek et al. teach a composition that contains chicken zona pellucida glycoprotein ZPC (chZPC), and its use in generating an antibody response in rabbits when combined with the immunological adjuvants Freund's complete and incomplete adjuvant (see entire document, particularly page 1231, left column, second paragraph of the section titled Protein Sequencing and Immunological Procedures). The chZPC was prepared from naturally occurring sources, either from eggs or ovarian follicles (see, Preparation and Solubilization of Chicken pvm, page 1231, right column). Glycosylation of the protein was demonstrated by experiments using glycosidases (see page 1232, Glycosidase Digestion of chZPC, and Figure 9).

Waclawek et al. do not teach chZPC made as a recombinant protein, or that it is chemically or enzymatically synthesized outside of a living organism.

However, there is no indication that the way in which the zona pellucida protein is made alters its structural properties, and as such these limitations have not been assigned any patentable weight.

As indicated above, injection of chZPC into rabbits in the presence of Freund's complete adjuvant initiates the production of antibodies. The disclosed mechanism by which the compositions of the instant application cause sterility or contraception are through the production of antibodies that block interactions between the egg and sperm. As such, it is reasonable to conclude that the chZPC composition of Waclawek et al. has the functional properties of being an immunosterilant and an immunocontraceptive. Applicant is invited to show evidence that these functional limitations are not present in the composition of Waclawek et al.

Therefore, the teachings of the prior art anticipate the claimed invention.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
9/20/04

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
September 14, 2004